DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Premia Spine Ltd.
Mr. Ron Sacher
CEO
7 Giborey Israel Street
Ramat Poleg, 42504
Israel

July 17, 2015

Re: K150380
Trade/Device Name: ProMIS™ Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: June 15, 2015
Received: June 15, 2015

Dear Mr. Sacher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150380

Device Name
ProMIS™ Fixation System

Indications for Use *(Describe)*
The ProMIS™ Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The ProMIS™ Fixation System can be used in an open approach or a posterior, percutaneous approach with MIS instrumentation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
Premia Spine's ProMIS™ Fixation System

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7 Giborey Israel Street
Ramat Poleg, 42504, Israel

Phone: 972-54-4626602
Facsimile: 972-72-2281201
Contact Person: Mr. Ron Sacher

Date Prepared: June 12, 2015

Trade Name: ProMIS™ Fixation System
21 C.F.R. 888.3070 Pedicle screw spinal system.
NKB - orthosis, spinal pedicle fixation, for degenerative disc disease, Class III
MNH - orthosis, spondylolisthesis spinal fixation, Class II
MNI - orthosis, spinal pedicle fixation, Class II

Primary Predicate Device
1. THUNDERBOLT™ and LANCER™ Pedicle Screw Systems by Choice Spine, LP (K132049).

Intended Use / Indications for Use
The ProMIS™ Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The ProMIS™ Fixation System can be used in an open approach or a posterior, percutaneous approach with MIS instrumentation.

Device Description

The ProMIS™ Fixation System consists of 3 main parts:
1. ProMIS™ Fusion Rods: a straight or bent rod with various lengths.
2. Polyaxial Pedicle screws.
3. Setscrew.

All components are manufactured from Ti6Al4V per ASTM F136.

Performance Data

The ProMIS™ Fixation System was subjected to static compression, static torsion, and dynamic compression testing per ASTM F1717.

Substantial Equivalence

The subject and predicate systems are made from the same materials and are composed of similar components, including pedicle screws, fusion rods, and set screws. In addition, the diameter and length range of the screws used in the subject devices are within the range of screws cleared in the predicate system. The subject devices use 6.0 mm Ti alloy rods while the predicate system uses 5.5 mm Ti alloy or CoCr rods. Finally, the ProMIS System features very similar surgical instruments compared to the predicate devices. In particular, the ProMIS, like the predicate, has surgical instruments used for percutaneous insertion of pedicle screws via a tower system.

The ProMIS™ Fixation System is substantially equivalent to the THUNDERBOLT™ and LANCER™ Pedicle Screw Systems. The ProMIS™ Fixation System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the ProMIS™ Fixation System and its predicate devices raise no new questions of safety or effectiveness. Performance data demonstrate that the ProMIS™ Fixation System is substantially equivalent to THUNDERBOLT™ and LANCER™ Pedicle Screw Systems.

Conclusions

The ProMIS™ Fixation System is substantially equivalent to the predicate devices.